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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,194	03/24/2004	R. Elaine Fulton	NEL-0020	3760

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EXAMINER	
SALVOZA, M FRANCO G	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/807,194	FULTON ET AL.	
	Examiner	Art Unit	
	M. Franco Salvoza	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 3, 5 have been amended.

Claims 1-5 are pending and under consideration.

Claim Rejections - 35 USC § 112

WITHDRAWN

Claim 3 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant contends that amendment to claim 3 obviates the rejection.

Applicant's argument is considered and found persuasive. The rejection is withdrawn.

Claim Rejections - 35 USC § 103

WITHDRAWN

Claims 1-5 were rejected under 35 U.S.C. 103(a) as being unpatentable over Hu et al. in view of Lee et al.

Applicant contends that the submission of a 1.132 Declaration indicates that the invention disclosed in Hu et al. is derived from the inventors of the present application and therefore does not stand as a prior art reference.

Applicant's arguments are considered and found persuasive. The rejection is withdrawn.

Claim Rejections - 35 USC § 112

NEW

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites a method for detecting VEE using a genetically biotinylated single chain fragment variable antibody. Further claim 4 recites the method of claim 2 comprising preparing an immunocomplex sandwich, said sandwich consisting of VEE, biotinylated antibody, and other components. Claim 5 recites the method of claim 4 wherein a concentration ratio of biotinylated antibody to fluoresceinated polyclonal antibody.

It is not clear what the term "genetically biotinylated" means, as the specification does not contain an express definition of the term. Further it is not clear whether the biotinylated antibody recited in claims 4 and 5 refers to the "genetically biotinylated" antibody or another kind of biotinylated antibody (for example, chemically biotinylated).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 1 recites a method for detecting VEE using a genetically biotinylated single chain fragment variable Ab comprising reacting the genetically biotinylated scFv Ab with a sample containing VEE for observing antigen-binding activity and analyzing the reactant.

Claims 2, 3 recite the method of claim 1 wherein said genetically biotinylated scFv Ab is a genetically streptavidin-binding peptide tagged recombinant biotinylated scFv Ab; wherein said Ab has streptavidin-binding activity.

Claim 4 recites the method further comprising the IFA assay; claim 5 further recites a concentration ratio of biotinylated Ab to fluoresceinated polyclonal Ab.

In making a determination as to whether an application has met the requirements for enablement under 35 U.S.C. 112 P 1, the courts have put forth a series of factors. See, In re Wands, 8 USPQ2d 1400, at 1404 (CAFC 1988) and Ex Parte Forman, 230 U.S.P.Q. 546 (BPAI 1986). The factors that may be considered include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. Id. While it is not essential that every factor be examined in detail, those factors deemed most relevant should be considered.

In this case, the amount of direction or guidance presented; the presence of absence of working examples, the quantity of experimentation necessary are most relevant.

As indicated above, claim 1 recites a method for detecting VEE using a genetically biotinylated single chain fragment Ab comprising reacting the Ab with a sample containing VEE for observing antigen-binding activity.

Applicant's disclosure indicates that the present inventors genetically fused a gene encoding a streptavidin-binding peptide to an anti VEE- scFv gene wherein the fusion antibody not only retained VEE-antigen binding specificity but also possessed streptavidin binding activity [0024].

However, it is not clear from the disclosure how to make or genetically fuse the genes in order to create a scFv that possesses these properties. In addition, it is not clear from the disclosure how to use the scFv or what is involved in the reacting step between the scFv Ab and the sample containing VEE for observing antigen-binding activity. While the antibody is intended to bind to VEE upon its inclusion in a sample, it is not clear whether or not that is the only property or even only intended property of the Ab.

The disclosure recites the already finished products of genetically biotinylated antibodies throughout the rest of the specification, including paragraph [0037], then recites merely biotinylated Abs in paragraph [0041]. The rest of the specification merely teaches optimizing ratios for determining assay sensitivities using the already finished products of the genetically biotinylated antibodies without a supporting disclosure of how to make the genetically biotinylated Abs or how to use them in such an assay by merely reacting the Ab with a VEE sample.

In view of these factors, the specification has not provided sufficient information to enable those in the art to practice the claimed invention without undue experimentation.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to M. Franco Salvoza whose telephone number is (571) 272-8410. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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